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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,626	03/09/2001	Leslie Lobel	62259/JPW/SHS	5559

7590 04/19/2005

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EXAMINER

JIANG, DONG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/804,626

Applicant(s)

LOBEL ET AL.

Examiner

Dong Jiang

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,7,16,18 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,7,16,18 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED OFFICE ACTION

The request filed on 04 January 2004 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/804,626 is acceptable, and a RCE has been established. An action on the RCE follows.

Applicant's response filed on 04 January 2004 is acknowledged.

Currently, claims 1, 2, 4, 7, 16, 18, and 24-26 are pending, and under consideration.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 7, 16, 18, and 24-26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hsueh et al., US5,925,549, and McCoy et al., US5,270,181, for the reasons of record set forth in the previous Office Actions mailed on 05 December 2003, and 06 April 2004.

Applicants argument filed on 04 January 2004 has been fully considered, but is not deemed persuasive for reasons below.

At pages 2-4 of the response, the applicant argues that the examiner has failed to establish a *prima facie* case of obviousness as the cited references fail to provide a reasonable expectation of success; that this invention provides a soluble fusion protein, which does not contain any of the gonadotropin receptor's transmembrane or intracellular domains; that prior to the instant invention, there existed uncertainty in the art as to whether a functional extracellular domain of said receptor could be expressed, and one skilled in the art could not have known whether the transmembrane region of the receptor was required of the receptor binding to occur, and could not have reasonably expected that the claimed fusion protein would succeed absent experimentation because of the uncertainty in the art concerning the receptor domains necessary for ligand binding. This argument is not persuasive because the art had established, prior to the instant application, that the extracellular domain of the hLH/CG receptor is sufficient for its ligand binding. For instance, Hsueh has demonstrated that the extracellular domains of both hLH/CG and FSH receptors in the fusion protein exhibit comparable ligand binding specificity to that of the wild type receptors (Examples 1 and 2 in columns 23 and 14, and Figures 2A and 2B). As another example, Lobel et al. (Endocrinology, 1997, 138(3):1232-1239) teaches, citing the prior art, that the extracellular domain of the hLH/CG receptor contains the binding site for hLH and hCG (page 1232, the right column, line 7 from the bottom). Lobel further demonstrates the expression of the extracellular binding domain of the hLH/CG receptor as a fusion with the cpIII filamentous phage coat protein, and the same binding specificity of the fusion phase as the wild type receptor (the abstract). Therefore, it was well defined that the extracellular domain of the hLH/CG receptor bear the ligand binding site prior to applicants invention.

Note: the newly cited reference is used to rebut applicants argument, and it is not for sustaining any new ground rejection.

Conclusion:

No claim is allowed.

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Advisory Information:

This is a RCE based on parent Application No. 09/804,626. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Elizabeth C. Kemmerer

**ELIZABETH KEMMERER
PRIMARY EXAMINER**

Dong Jiang, Ph.D.
Patent Examiner
AU1646
4/8/05